Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2170513	07/14/2022
Name of Provider or Supplier	**Street Address, City, State**	
Amg Ada Advanced Care Oncology And	657 Willow Grove Street Suite 305, Hackettstown, NJ	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the Laboratory Director failed to sign attestation statements for Hematology/Coagulation 1st event 2022, all events 2021 and 2nd, 3rd events 2020 with the American Proficiency Institute (API). The TP confirmed on 7/14 /22 at 10:00 am that PT records were not maintained.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to retain all QC records for tests performed on the Sysmex XP-500 analyzer from 2/4/22 to the date of survey. The finding includes: 1. There was no record of QC past March 2022. 2. The TP confirmed on 7/14/2022 at 11:00 am that the all QC records were not retained.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Operators Manual (OM) and interview with the Testing Personnel (TP), the laboratory failed to have all procedures written for Hematology tests performed in on the Sysmex XN-550 analyzer from 2/4/2022 to the date of the survey. The findings include: 1. The PM stated "Complete this section with your Laboratory policy for documenting and retaining commercial controls and X=barM data" 2. The laboratory had two policies on Quality Control verification. 3. The PM states "Follow laboratory protocol for troubleshooting Quality Control results exceeding the upper or lower limit of acceptability. Complete this section with you laboratory's QC action plan for out of range commercial control products and X-barM" 4. On page 26 the PM states "refer to the Sysmex XN-L series automated hematology systems flagging interpretation guild for additional information on flagging". a. The laboratory did not have the aforementioned guild. 5. The TP confirmed on 7/14/22 at 10:30 am that the laboratory did not have all procedures written for Hematology tests.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of Quality Control (QC) material in use, Manufacture Package Insert (MPI) and interview with the testing Personnel (TP), the laboratory failed to put expiration dates on QC material for Hematology tests run on the Sysmex XN-550 analyzer at the time of survey. The TP confirmed on 7/14/22 at 11:45 am the laboratory failed to put expiration dates on the control material.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the

	laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of the Sysmex Certificate of Calibrations (COC) and interview with the Testing Personnel (TP), the laboratory failed to perform calibration verification every 6 months on the Sysmex XN-550 analyzer used for Hematology testing. The findings include: 1.There was no documentation of the number, type and concentration of the materials used for performing Calibration Verification (CV). 2. The COC did not provide lot numbers of calibration material used for CV. 3. The TP confirmed on 7/14/22 at 10:00 am that the laboratory failed to perform CV every 6 months.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual PM, Quality Control (QC) records, and interview with the Testing Personnel (TP) the laboratory failed to have available Corrective Action (CA) procedures for QC from 2/4/22 to the date of survey. The TP confirmed on 7/14/22 at 11:00 am that the laboratory failed have available Corrective Action (CA) procedures.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on review of Procedure Manual (PM), Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to establish written policies and procedures to monitor, assess and correct problems identified in the analytic system for Hemtology tests perfomed on the Sysmex XN-550 from 2/4/20 to the date of the survey. The findings include: 1. There was no evidence that QC verification was reviewed. 2. The PM procedure "C. Frequency of Control use and review" states "complete this section with your laboratory's policy for commercial and patient control analysis and review frequency". 3. The TP confirmed on 7/14/22 at 10: 40 pm the laboratory did not have a procedure to monitor and assess problems for Hemtology tests perfomed on the Sysmex XN-550.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the Laboratory Director (LD), failed to ensure that all PT results received were reviewed by the appropriate staff to identify any problems that require corrective action for Hematology performed with the American Proficiency Institute (API) in the calendar years 2020, 2021 and the first event of 2022. The TP confirmed on 7/14/22 at 9:45 am that the PT results were not reviewed.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records, Procedure Manual (PM) and interview with the Testing personnle (TP), the Laboratory Director failed to ensure that the QC program was maintained for laboratory services provided from 2/4 /20 to the date of the survey. The findings include: 1. The QC plan in the PM was not completed 2. There was no documented corrective action when QC analytes were flagged and rerun. 3. The TP confirmed on 7/14/22 the LD did not ensure the QC plan was maintained. .

D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a lack of a Quality Assurance (QA) plan and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a QA plan from 2/4/20 to the date of the survey. The TP confirmed on 7/14/22 at 11:30 am that a QA plan had not been established.